



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,707	01/10/2002	Mario G. Cardozo	9/182-1-C1	3260
28509	7590	09/15/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION			LY, CHEYNE D	
900 RIDGEBURY ROAD			ART UNIT	
P O BOX 368			PAPER NUMBER	
RIDGEFIELD, CT 06877			1631	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,707	CARDOZO ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

1. Applicants' arguments filed July 07, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 1 and 2 has been acknowledged.
3. Claim 3 is examined on the merits.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The instant rejection has been necessitated by claim amendments.
7. Specific to line 1, the phrase "most efficient synthesis" causes the claim to be vague and indefinite because the body of the claim recites steps which ends in "reviewing the results...for synthesis" without reciting any steps for the most efficient synthesis. Which step(s) of claim 1 supports the limitation of "determining the most efficient synthesis? Clarification of the metes and bounds of the instant claim is required.
8. Specific to step (d), line 2, the phrase "the ordered lists" causes claim 3 to be vague and indefinite because it is unclear whether said phrase is directed to the first

Art Unit: 1631

ordered list, or an unspecified ordered lists. The same issue is present in step (e).

Clarification of the metes and bounds is required.

9. Specific to step (h), the limitation of “from step (g) to generate a ranking or order for synthesis” causes the claim to be vague and indefinite because step (g) repeats steps a) through f) until all clusters have been eliminated. Step (g) eliminates all clusters, therefore, what is being ranked or ordered in step (h)? Clarification of the metes and bounds is required.

CLAIM REJECTIONS - 35 U.S.C. § 112, FIRST PARAGRAPH

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER.

12. The instant rejection has been necessitated by claim amendments.

13. The limitations recited in lines 1-7 and step (h) have not been found in the instant specification. It is noted that Table I (page 6) discloses a ranking of substituents. However, the specific disclosure does not provide written description basis support for the broader limitation of “generate a ranking or order for synthesis.”

CLAIM REJECTIONS - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 3 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Terrett (1998).

16. The instant rejection has been necessitated by claim amendments.

RESPONSE TO ARGUMENT

17. Applicant argues that Terrett does not disclose how to synthesize a chemical library in an efficient manner. Applicant's argument has been fully considered and found to be unpersuasive because claim 1 does not recite any steps for the achieving the most efficient synthesis as discussed above.

18. Further, because the Office does not have the facilities for examining and comparing the applicant's claimed method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art. See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

REJECTION RE-ITERATED

19. Terrett discloses a method of generating (synthesize) monomers of various lengths wherein the common substituent is a the N-terminus amino acid being protected with a Boc or Fmoc group; and said monomers are divided into portions

Art Unit: 1631

and excess monomer and coupling agents are removed (page 16, lines 2-9), as in steps (a) and (b).

20. The process is repeated for a total of n times to generate the compounds of table 2.1 of the first order to the n th order (page 16, line 20-21 and Table 2.2), as in steps (c) and (d).

21. The number of compounds is obtained by the increase in the products of case x to the power of n (page 16, lines 20-21), as in step (e).

22. The iterative process of Terrett demonstrates the elimination of clusters to identify the most active (ranking and efficient) for synthesis (pages 17-18 and Figures 2.8 and 2.9), as in steps (f) to (h).

CONCLUSION

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1631

25. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

26. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

27. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Art Unit: 1631

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
8/13/04

Ardin H. Marschel 9/12/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER